

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Serial No.	10/664,715	Confirmation No.:	4404
Applicant(s)	Dimitrios Manoussakis	Examiner:	P. Kathryn Wright
Filed:	September 18, 2003	Docket:	P-5808/1
Group Art Unit:	1743	Customer No.:	26253
Title:	High Bias Gel Tube and Process For Making Tube		

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Appellant appeals the rejections set forth in the Office Action mailed on April 29, 2010. This Appeal Brief is submitted in furtherance to the Notice of Appeal electronically filed on October 29, 2010. The Notice of Appeal appeals the rejection of claims 14, 16-18, 20-24, 26-28 and 30-32 advanced in the April 29, 2010 Office Action. The headings used hereinafter and the subject matter set forth under each heading are in accordance with 37 C.F.R. § 41.37. Submission of a brief in support of the appeal in this case is due by Tuesday May 31, 2011 with a five month extension of time as Monday May 30, 2011 is a Federal Holiday. Accordingly, this brief is being timely filed.

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I. REAL PARTY IN INTEREST

Becton, Dickinson and Company, having its principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417, is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to the Appellant, the Appellant's legal representative, or the Assignee of the above-identified application which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF THE CLAIMS

Claims 14, 16-18, 20-24, 26-28 and 30-32 are pending in the present application and are the subject of this Appeal. Claim 14 is in independent form, with the remaining claims dependent thereon.

Claims 14, 16-18, 20-24, 26-28 and 30-32 stand rejected under 35 U.S.C. 103(b) for obviousness based on EP Patent No. 1 107 002 A2 to Hugh Conway (hereinafter "Conway").

Each of these claims has been rejected at least twice. All other claims have been withdrawn (Claims 1-13, 33-60 and 67-86) or cancelled (Claims 15, 19, 25, 29, and 61-66) and are not part of this Appeal.

IV. STATUS OF AMENDMENTS

All amendments previously made to the claims have been entered. The claims have not been amended after being rejected in the April 29, 2010 Office Action. A copy of the claims, as presently pending, is provided in the Claims Appendix attached hereto.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 14 is directed to a container or tube (10). (*See* Figs. 1 and 3.) The tube (10) includes an upper end (12), a lower end (14) and sidewalls (16) having an inner wall (18) and an outer wall (20) (*See* Figs. 1 and 3; *see also* page 2, paragraph [0012].) A thixotropic gel (22) is located within the container (10), in contact with a portion of the inner wall (18). (*See* Figs. 1 and 3; *see also* page 2, paragraph [0012].) The thixotropic gel (22) further includes continuous first (40) and second (42) regions, the first region (40) located at or adjacent to the lower end (14), and the second region (42) extending upward from a portion of the first region (40). (*See* Fig. 3; *see also* page 4, paragraph [0019].) The first region (40) includes an imaginary upper boundary (44) at which the first region (40) exhibits 360° circumferential contact with the inner wall (18). (*See* Fig. 3; *see also* page 4, paragraph [0020].) Furthermore the first region (40) includes at least about 80 vol.% of the thixotropic gel (22). (*See* page 4, paragraph [0022].)

Other than claim 14, there are no other independent claims involved in this Appeal.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Based upon the rejections presented in the Office Action dated April 29, 2010 Appellants present the following grounds of rejection to be reviewed on Appeal:

Whether claims 14, 16-18, 20-24, 26-28 and 30-32 were properly rejected under 35 U.S.C. 103(b) for obviousness based on EP Patent No. 1 107 002 A2 to Hugh Conway (hereinafter "Conway").

VII. ARGUMENT

Claims 14, 16-18, 20-24, 26-28 and 30-32 were improperly rejected under 35 U.S.C.

103(a) for obviousness based on Conway.

Claims 14, 16-18, 20-24, 26-28 and 30-32 stand rejected under 35 U.S.C. 103(b) for obviousness based on EP Patent No. 1 107 002 A2 to Hugh Conway ("Conway").

In view of the following remarks, Appellants respectfully request reversal of this rejection.

The present claimed invention relates to an improved fluid collection container, containing a gel separation medium (22) that is disposed in the tube (10) in a manner and geometry which overcomes potential gel movement issues. (See Figs. 1 and 3; *see also* pages 1 and 2, paragraph [0003].)

Of the claims rejected, claim 14 is independent, with the remaining claims dependent thereon.

Claim 14 recites among other things:

*a thixotropic gel in contact with a portion of the inner wall,
wherein the thixotropic gel comprises continuous first and second regions, the first region located at or adjacent to the lower end, and the second region extending upward from a portion of the first region, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel.*

Appellants submit that Conway fails to disclose, teach or suggest at least the claimed features of:

- a) A thixotropic gel in contact with a portion of the inner wall.
- b) The first region exhibiting 360° circumferential contact with the inner wall.
- c) The first region comprising at least about 80 vol.% of the gel.

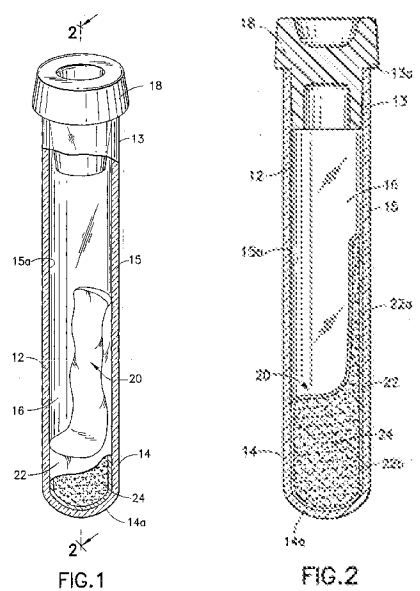
Each of these features will be discussed in detail in the following pages.

Conway fails to disclose, teach or suggest at least the claimed features of:

a) A thixotropic gel in contact with a portion of the inner wall.

b) The first region exhibiting 360° circumferential contact with the inner wall.

Conway is directed to a container (tube 12) having an upper end 13 and lower end 14 and a cylindrical wall 15 extending therebetween in which a thixotropic gel 24 is contained within a deformable container or flexible bag 22. Bag 22 is in frictional engagement with the inner surface 15a of cylindrical wall 15 (see Figs. 1 & 2, shown below).



Thus Conway fails to disclose or teach or suggest a container in which the gel is in contact with the inner wall of the container and that the first region (of the gel) exhibits 360° circumferential contact with the inner wall.

The Examiner states in the Office Action dated April 29, 2010:

“Conway does not specifically disclose the gel in contact with a portion of the inner wall of the container. However, the use of thixotropic gel materials as a direct barrier for moving into an area adjacent the two phases of the sample being separated in order to maintain the components separated for subsequent examination of the individual components is well known in the art (see paragraphs [0002]-[0005] of Conway). The thixotropic gels used in separating blood components are typically chemically inert to most analytes present in blood samples. Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to eliminate the flexible bag from the device of Conway since the use of such bags increases the manufacturing cost and complexity of the device.”

Appellants respectfully submit that Conway teaches away from the use of a thixotropic gel in direct contact with a blood sample or its separated components by disclosing the following disadvantages with traditional gel separators for blood:

- i) unbound resin may be released from the gel mass into the sample, and
 - ii) no commercially available gel is completely chemically inert to all analytes,
- (see paragraphs [0004] and [0005] shown below, emphasis added).

[0004] The most widely used device includes thixotropic gel material such as polyester or silicone gels. The present gel serum separation tubes require special manufacturing equipment to prepare the gel and to fill the tubes. Moreover, the shelf-life of the product is limited in that over time unbound resin may be released from the gel mass. This resin may have a specific gravity that is less than or equal to the separated serum and may float in the serum and may clog the measuring instruments such as the instrument probes used during the clinical examination of the sample collected in the tube. Such clogging can lead to considerable downtime for the instrument to remove the clog.

[0005] In addition, no commercially available gel is completely chemically inert to all analytes. If certain drugs are present in a blood sample when it is taken, there can be a chemical reaction at the gel interface.

Therefore Conway teaches the encapsulation of the gel separator within a deformable container or flexible bag in order to prevent direct contact between the gel and blood sample.

Thus one skilled in the art would have no motivation whatsoever to eliminate the flexible bag from the device of Conway.

The Examiner maintains that the thixotropic gels used in separating blood components are considered chemically inert to most analytes present in blood samples in the prior art.

Appellants submit that Conway has been cited by the Examiner as the only reference to provide a case of prima facie obviousness.

Conway explicitly teaches that no commercially available gel is completely chemically inert to all analytes (see paragraph [0005]). If certain drugs are present in a blood sample when it is taken, there can be a chemical reaction at the gel interface.

Therefore according to Conway one skilled in the art cannot consider the thixotropic gels used in separating blood components to be chemically inert to most analytes present in blood samples.

Appellants respectfully submit that the intended purpose of Conway (as disclosed in paragraph [0006]) is a separator device that among other things:

- (i) is easily used to separate a blood sample;
- (iv) employs the benefits of a thixotropic gel barrier yet avoids the many disadvantages of placing a gel in contact with the separated blood components;
- (vi) minimizes entrapment of the lower and higher density materials within the separator device;

Furthermore Conway teaches (see paragraphs [0010] and [0011]) that the assembly of the present invention (of Conway) has the following advantages over existing separation products that use gel:

- i) One advantage is that the assembly of the present invention (of Conway) will not interfere with analytes as compared to gels that may interfere with analytes. In particular, the assembly (of Conway) will not interfere with therapeutic drug monitoring analytes.
- ii) Another notable advantage of the present invention (of Conway) is that fluid specimens are not subjected to low density residuals such as unbound resins that are at times available in products that use gel.

Thus elimination of the bag from the separator device of Conway would be contrary to the nexus of the teaching of Conway and negate the disclosed advantages over the prior art separation products.

The Office should also note, according to MPEP §2143.01 Section VI, that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Furthermore, Section V of the MPEP §2143.01 states, that if a proposed modification would render the prior art invention modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In *re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The elimination of the flexible bag from the device of Conway results in a change in the principle of operation of the separator and according to the teachings of Conway would render the modified prior art invention unsatisfactory for its intended purpose by placing a gel in contact with the separated blood components and allowing entrapment of the lower and higher density materials within the separator device.

The Examiner further proposes in the Office Action dated April 29, 2010, pages 6 and 7, (emphasis added):

While the Conway reference stresses the use of a bag to prevent clogging and "possible" chemical interaction with they are concerned. They are part of the literature of the art, relevant for all they contain. See In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) and In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) in which the court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed." See also MPEP § 2131.05 and § 2145, subsection XD.

Appellants note that Conway reference reasonably suggests to one skilled in the art the use of a thixotropic gel contained within a deformable container or flexible bag to prevent contact with the blood sample. Furthermore Conway fails to teach any embodiments (preferred or non-preferred) which do not have a thixotropic gel contained within a deformable container or flexible bag.

Appellants respectfully submit that MPEP § 2131.05 discusses Nonanalogous or Disparaging Prior Art in terms of anticipatory prior art and not obviousness and therefore is not relevant as Conway does not anticipate the claimed invention.

For these reasons, Appellants respectfully submit that Conway fails to teach or suggest a container having a thixotropic gel in contact with a portion of the inner wall and therefore the first region exhibiting 360° circumferential contact with the inner wall.

Appellants further submit that Conway fails to disclose, teach or suggest at least the claimed feature of c) the first region comprising at least about 80 vol.% of the gel.

Conway is completely silent in regard to the vol.% of gel within the first region.

The Examiner proposes in the Office Action of April 29, 2010 that “it can be reasonably assumed that the first region of the gel comprises at least about 80 vol. % of the thixotropic gel.”

Appellants respectfully disagree with the Examiner's assumptions regarding Conway.

First, Conway does not indicate the drawings (Figs. 1 and 2) were drawn to scale. It is well known that proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale. See MPEP §2125. When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. It is well established that

patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.

Second, Conway only discloses that “the gel 24 substantially fills the first portion 22b of the bag 24 with only remaining second portion 22a being substantially absent of gel” (see paragraph [0028]). Thus one skilled in the art cannot reasonably conclude as to what the term “substantially” means in relation to vol.% of gel when no guide or ranges are provided by the disclosure of Conway.

Appellants respectfully submit that Conway fails to teach or suggest a container having a thixotropic gel in contact with a portion of the inner wall, wherein the first region exhibits 360° circumferential contact with the inner wall, and the first region comprising at least about 80 vol.% of the gel.

VIII. CONCLUSION

For the reasons set forth above, Appellants submit that claims 14, 16-18, 20-24, 26-28 and 30-32 are indeed patentable over the cited art and are in condition for allowance. Reversal of all of the Examiner's rejections and remand of this case to the Examiner are respectfully requested.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact applicants' agent at the telephone number set forth below.

Respectfully submitted,

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Dated: May 31, 2011.
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Doc# 1287852v1

CLAIMS APPENDIX

14. A container comprising:

an upper end, a lower end, and a sidewall between the upper and lower ends
having inner and outer walls; and

a thixotropic gel in contact with a portion of the inner wall,

wherein the thixotropic gel comprises continuous first and second regions, the
first region located at or adjacent to the lower end, and the second region extending
upward from a portion of the first region, wherein the first region comprises an imaginary
upper boundary at which the first region exhibits 360° circumferential contact with the
inner wall, and wherein the first region comprises at least about 80 vol.% of the
thixotropic gel.

16. The container of claim 14, wherein the imaginary upper boundary exhibits a
best fit plane within 10° of a plane perpendicular to the longitudinal axis of the tube.

17. The container of claim 14, wherein the uppermost point of the second region
is located at least about 8 mm higher than the uppermost point of the first region.

18. The container of claim 17, wherein the distance is about 8 to about 21 mm.

20. The container of claim 14, wherein the first region comprises about 80 to about 95 vol.% of the thixotropic gel.

21. The container of claim 14, wherein the interior surface of the thixotropic gel at the intersection of the first and second regions exhibits a radius of curvature between about 4 and about 8 mm.

22. The container of claim 14, wherein a best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 25° or less with a plane substantially perpendicular to the longitudinal axis of the container.

23. The container of claim 22, wherein the exposed surface of the second region facing the interior of the container defines a best-fit plane exhibiting a 45 to 90° angle with a plane substantially perpendicular to the longitudinal axis of the container.

24. The container of claim 14, wherein the best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 90 to 140° with the best-fit plane to the surface of the second region facing the interior of the container.

26. The container of claim 14, wherein, along a plane perpendicular to the longitudinal axis of the container located halfway between the average height of the

exposed surface of the first region and the uppermost point of the second region, the second region exhibits 80 to 140° circumferential contact with the inner surface.

27. The container of claim 14, wherein the entirety of the second region exhibits less than 180° circumferential contact with the inner wall.

28. The container of claim 27, wherein the entirety of the second region exhibits less than 120° circumferential contact with the inner wall.

30. The container of claim 14, wherein the container is a tube.

31. The container of claim 30, wherein the tube comprises a pierceable closure therein.

32. The container of claim 14, wherein the lower end is closed, and wherein the thixotropic gel is disposed at the closed lower end.

Application No. 10/664,715

Response Under 37 C.F.R. § 41.37, Appellant's Brief dated May 31, 2011

In Reply to USPTO Correspondence of December 29, 2010

Docket No.

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EVIDENCE APPENDIX

None.

Application No. 10/664,715

Response Under 37 C.F.R. § 41.37, Appellant's Brief dated May 31, 2011

In Reply to USPTO Correspondence of December 29, 2010

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RELATED PROCEEDINGS APPENDIX

None.